

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Chatterjee et al.

Serial No.: 08/372,676

Filing Date: 01/07/95

For: Anti-idiotypic monoclonal antibody 1A7
and use for the treatment of melanoma and
small cell carcinoma

Examiner: J. Reeves

Group Art Unit: 1813

DECLARATION UNDER 37 CFR 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, MALAYA BHATTACHARYA-CHATTERJEE, Ph.D., do hereby declare as follows:

1. Under the name Malaya Chatterjee, I am an inventor for the above-referenced patent application.
2. I am a Member of the Markey Cancer Center in Lexington, and am an Associate Professor in the Department of Internal Medicine, University of Kentucky. My research expertise includes the fields of immunochemistry and molecular oncology. A copy of my *curriculum vitae*, describing my background and qualifications, accompanies this Declaration as *Exhibit A*.

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3. In collaboration with the other inventors of the above-referenced patent application, I developed and cloned the 1A7 antibody-producing hybridoma cell line.

4. The cell line was obtained after repeated immunization of BALB/c mice with purified antibody 14G2a. Spleen cells from 4 immunized mice were fused with non-producing mouse myeloma cells and plated in 1200 wells. Supernatants from one of the wells was found to contain antibody reactivity specific for 14G2a but not for isotype or allotype controls. The antibody was also able to inhibit the binding of labeled 14G2a to GD2 expressed on a human cell line. The antibody-producing cells from this well were designated 1A7-1A1. The cells were subsequently cloned by two rounds of limiting dilution. This re-cloned line and the antibody produced thereby are referred to in the above-referenced patent application as 1A7.

5. Progeny of antibody-producing cells from the re-cloned line have been deposited with the ATCC under Accession No. BH-11786. Antibody from the cells has been characterized as described in the above-referenced patent application, and is claimed therein.

6. The 1A7-1A1 cells, the re-cloned 1A7 cell line, the predecessors and progeny thereof, and the antibody produced thereby has been maintained exclusively under the control of myself and the other inventors of the above-referenced application. The cells have been provided outside my laboratory to Dr. Sunil Chatterjee for purposes of ascertaining the sequence of the 1A7 variable region. The transfer was made with the agreement that the cells and the antibody not be redistributed, and that information on the sequence be kept confidential. Purified 1A7 antibody recently entered clinical trials at the University of Kentucky under strict supervision of

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Dr. Ken Foon, co-inventor of the patent application. Neither the antibody nor the antibody-producing cells have been available to the public at any time.

7. The DNA and amino acid sequences of the 1A7 variable region genes were determined by Dr. Sunil Chatterjee under my auspices some time after the filing of the above-referenced patent application on January 7, 1995. The 1A7 sequence data have not been disclosed except under terms of confidentiality. The data were included in a recent grant application made to the National Institutes of Health under terms of confidentiality, and it is my understanding that the data will remain confidential until the grant is approved. It is my understanding that a decision on the application has not yet been rendered.

8. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

3/11/96

Date

Malaya Bhattacharya-Chatterjee

Malaya Bhattacharya-Chatterjee, Ph.D.

CURRICULUM VITAE**I. General Information**

NAME: Malaya Bhattacharya-Chatterjee, Ph.D.

HOME ADDRESS: 2400 The Woods Lane, Lexington, Kentucky 40502
HOME TELEPHONE: 606-269-2225

OFFICE ADDRESS: 207 Combs Research Bldg
University of Kentucky Medical Center
800 Rose Street
Lexington, KY 40536-0096
OFFICE TELEPHONE: 606-257-8210

FAX: 606-257-8940

E-MAIL: mchatter@uklans.uky.edu

SOCIAL SECURITY NO.: 077-46-3416

DATE AND PLACE OF BIRTH: January 16, 1946 - Cooch-Behar, India

PRESENT NATIONALITY: U.S. Citizen

MARITAL STATUS: Married, two children

SPOUSE NAME: Sunil K. Chatterjee, Ph.D.

CHILDREN: Indranil Chatterjee (7/16/77)
Sumana Chatterjee (6/21/80)